Remarks

Claims 1-4 (amended), 5-6, 12 (amended), 13, 14 (amended), and 15-17 (new) are pending. Claims 7-11 have been cancelled. Applicants respectfully request reconsideration of this application.

Restriction Requirement

The Office Action required restriction between claims 1-7 and 12-14 directed to an apparatus, and claims 8-11 directed to a method. Applicants hereby elect to prosecute claims 1-7 and 12-14. Claims 8-11 have been cancelled.

Information Disclosure Statement

The Office Action stated that several foreign language references submitted as part of two previously submitted Information Disclosure Statements were not considered because they failed to comply with 37 C.F.R. 1.97 and 1.98. Specifically, the Office Action stated that the references were not accompanied by a translation.

37 C.F.R. 1.98 does not require the Applicants to submit a translation of all non-English references, but does require Applicants to submit a concise explanation of all non-English references. A Supplemental Information Disclosure Statement that includes concise explanations of all non-English references cited in both previously filed Information Disclosure Statements accompanies this Amendment.

Claim Amendments

Claim 1 has been amended to recite an apparatus for treating sphincter deficiencies including a syringe containing a bulking agent, a hypodermic needle having a linear segment extending from a hub of the syringe and an arcuate segment formed by a bend located closest to a tip of the needle. Claim 1 has further been amended to recite that the apparatus is configured to inject a bulking agent into a tissue plane between an esophagus, rectum or urethra and a surrounding sphincter muscle. Amended claim 1 is fully supported by the

application and claims as originally filed. Claim 12 has been amended to eliminate the penetration depth shield feature and to recite that the syringe contains a bulking agent.

New claim 17 recites an instrument for treating sphincter deficiencies comprising a syringe adapted to contain a bulking agent, and a needle extending between about 1.5 and 5 inches from the syringe. The needle has a linear segment and an arcuate section formed by about a 15 degree bend. This claim is fully supported by the specification and claims as originally filed.

Claim Rejections

Claims 1-5 and 7 were rejected under 35 U.S.C. 102(a) as being anticipated by the Carbon Medical Technologies Memo dated October 23, 2001 ("the Memo").

Applicants respectfully submit that the Memo is not a proper 35 U.S.C. § 102(a) reference because the Memo was prepared after Applicants conceived and reduced the claimed invention to practice.

Applicants enclose the Declaration of co-inventor Kristina Wittchow (the "Declaration"). As stated in the Declaration, Ms. Wittchow is employed by Carbon Medical Technologies in the position of Vice-President, Technical and Professional Services. The Declaration further states that Ms. Wittchow, with the assistance of additional employees of Carbon Medical Technologies, prepared the Memo after the claimed invention was jointly conceived and reduced to practice by the inventors named in the present application. Applicants respectfully request withdrawal of this rejection.

Claims 1, 5-6 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,258,067 to Hill. The Office Action stated that Hill reports an apparatus including a syringe, a hypodermic needle and a 5-45 degree bend.

Claim 1 has been amended to recite that the syringe houses a bulking agent and that the apparatus is configured to inject a bulking agent into a tissue plane between an esophagus, rectum or urethra and a surrounding sphincter muscle. Claims 5 and 6 depend from claim 1.

Applicants respectfully submit that Hill does not anticipate claims 1, 5 or 6 because Hill does not report an instrument that houses a bulking agent and that is adapted to inject a bulking agent. Hill reports a middle ear fluid aspirator including a negative pressure syringe and an angled needle to facilitate fluid aspiration while maintaining visual contact with the tympanic membrane of the ear. This negative pressure syringe assembly is reportedly used to withdraw fluids from a patient's middle ear by depressing a handle. Because the assembly reported in Hill is limited to suction applications, the assembly does not teach or suggest an apparatus for injecting a bulking agent into a tissue plane between an esophagus, rectum or urethra and a surrounding sphincter muscle as claimed. Applicants respectfully request withdrawal of this rejection.

Claims 1-2 and 5-6 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 1,569,174 to Crowther, in particular by Figure 4. The Office Action stated that Crowther discloses an apparatus including a syringe and a needle with a 15 degree bend. The Office Action cited Figure 4 in support of this assertion.

As previously noted, Claim 1 has been amended to recite that the syringe houses a bulking agent and that the instrument is configured to inject a bulking agent into a tissue plane between an esophagus, rectum or urethra and a surrounding sphincter muscle. Claims 2, 5 and 6 depend from claim 1.

Applicants respectfully submit that Crowther does not anticipate the claimed invention because the needle reported in Crowther is not reported to inject a bulking agent into a tissue plane between an esophagus, rectum or urethra and a surrounding sphincter muscle as claimed, and in particular, because Crowther is silent with respect to needle lengths and bend angles.

Crowther generally reports a hypodermic needle with an improved fitting for connection to a syringe (page 1, lines 9-16). The fitting may be used with straight or bent needles (page 2, lines 63-65). However, Crowther does not report specific medical applications for the needle, and is silent with respect to particular bend angles, needle lengths and needle diameters that could be utilized as part of the reported needle. Thus, Crowther does not report a needle that is necessarily configured to inject a bulking agent into a tissue

plane between an esophagus, rectum or urethra and a surrounding sphincter muscle as claimed.

To the extent that the Office Action relies on an actual measurement of the bend in the needle shown in Fig. 4 for its assertion that Crowther describes a 15 degree bend, Applicants submit that an actual measurement of the illustrated needle, unless supported in the specification, is not a proper basis for a prior art rejection. See MPEP § 2125 (stating that when a reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing figures are of little value). As previously noted, Crowther is silent with respect to measurements, and likewise does not state that that the drawings were prepared to scale. Applicants respectfully request withdrawal of this rejection.

Claims 1, 3-6 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,518,38 to Evans. The Office Action stated that Evans reports an apparatus including a syringe and a needle with a 20 degree bend and needle length of about 1.5-60 inches or 1.5-5 inches.

Applicants respectfully submit that Evans does not anticipate claim 1 because the device reported in Evans does not include a syringe housing a bulking agent. Instead, Evans reports an instrument and method for epidural and spinal anesthesia including outer and inner needle assemblies. The outer needle includes a portion having about a 20 degree bend. The inner needle is generally straight but is adapted to extend within and project from the outer needle assembly to deliver a medicament into the epidural region of a patient. However, Evans does not report or suggest attaching a syringe containing a bulking agent to the outer needle because Evans is directed to a method of delivering medicaments in the vicinity of a patient's spine. Applicants respectfully request withdrawal of this rejection.

Claims 1, 5-7 and 12-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,792,478 Lawin et al. in view of Hill. The Office Action stated that Lawin et al. reports the injection of a bulking agent, but does not disclose a bent needle or a depth shield. However, the Office Action stated that Hill reports a syringe having a bent needle and a syringe and that it would have been obvious to modify the delivery device

reported in Lawin et al. with a bent needle and a shield as reported by Hill to provide better maneuvering of the needle.

Applicants respectfully submit that a person of ordinary skill in the art would not have been motivated to combine Lawin and Hill because the instrument reported in Hill is configured to remove body fluids rather than to inject a bulking agent such as the bulking agent reported in Lawin.

As previously noted, Hill utilizes a negative pressure syringe assembly to withdraw fluids from a patient's middle ear by depressing a handle. Thus, the assembly reported in Hill is not adapted to inject a bulking agent, but rather, to withdraw fluids. Lawin reports the use of a plurality of particles for bulking various sites of the body. Lawin does not report the use of a bent needle to inject the particles, nor does Lawin report specific needle configurations for injecting a bulking agent into a tissue plane between an esophagus, rectum or urethra and a surrounding sphincter muscle as recited in amended claims 1 and 12.

Thus, a person of ordinary skill would not be motivated to inject the bulking material reported in Lawin with a device designed to withdraw fluids from the body. Even if combined as asserted by the Office Action, it does not appear that the instrument reported in Hill would be capable of injecting the bulking agent reported in Lawin. Applicants respectfully request withdrawal of this rejection.

New Claim

Applicants respectfully submit that new independent claim 17 would also be patentable over the cited references. Claim 17 recites an instrument including a syringe adapted to house a bulking agent and a needle having a length between about 1.5 and 5 inches and that includes an arcuate segment having about a 15 degree bend. None of the cited references report a needle having these features. Applicants respectfully request allowance of this claim.

CONCLUSION

All of the pending claims are in condition for allowance. Applicants request a notice to that effect. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully Submitted,

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